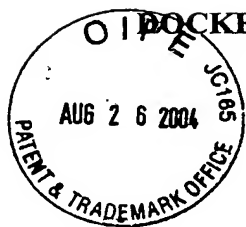


IFW



DOCKET NO.: ORTU-0007

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Raffa, et al.**

**Confirmation No.: 2441**

**Application No.: 10/761,096**

**Group Art Unit: 1614**

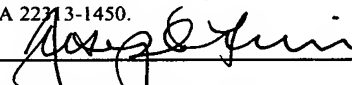
**Filing Date: January 20, 2004**

**Examiner: Dwayne Jones**

**For: COMPOSITION COMPRISING A TRAMADOL MATERIAL AND  
ACETAMINOPHEN AND ITS USE**

DATE OF DEPOSIT: AUG. 23, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

  
TYPED NAME: Joseph Lucci  
REGISTRATION NO.: 33,307

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

## EXCEPT THAT:


- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No.

, filed .

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: *AUG. 23, 2004*

  
\_\_\_\_\_  
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Sheet 1 of 2

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>ORTU-0007</b>	Application No. <b>10/761,096</b>
		Applicant <b>Raffa, et al.</b>	
		Filing Date <b>January 20, 2004</b>	Group <b>1614</b>
		Confirmation No. <b>2441</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>152</b>	Letter from Kurt Nielsen, Ph.D., to Ortho-McNeil Pharmaceutical, Inc., Re.: <i>Patent Certification Notice- U.S. Pat No. 5,336,691, Tramadol/Acetaminophen Tablets, 37.5 mg/325 mg, Teva Pharmaceutical USA, Inc., 's ANDA 76-914, January 22, 2004, 12 pages</i>	
	<b>153</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Kali's Supplemental Response to Ortho-McNeil's First Set of Interrogatories, <b>May 7, 2004</b>	
	<b>154</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Kali's Supplemental Response to Ortho-McNeil's Second Set of Interrogatories, <b>May 7, 2004</b>	
	<b>155</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Kali's Supplemental Response to Ortho-McNeil's Third Set of Interrogatories, <b>May 7, 2004</b>	
	<b>156</b>	Expert Report of Dr. Stefan Grond, with Attached Exhibits 1 thru 9, <b>May 26, 2004</b>	
	<b>157</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Declaration of Deirdre A. Clarkin, with Attached Exhibits 1 thru 18, <b>May 27, 2004</b>	
	<b>158</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Declaration of Pearl T.L. Siew, with Attached Exhibits 1 thru 12, <b>May 28, 2004</b>	
	<b>159</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Declaration of Daniel G. Brown, with Attached Exhibits 1 thru 23, <b>May 28, 2004</b>	
	<b>160</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Rule 56.1 Statement of Undisputed Material Facts for Defendant Kali Laboratories' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,336,691: Claim 6, <b>May 28, 2004, 12 pages</b>	
	<b>161</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Brief in Support of Defendant Kali Laboratories' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,336,691: Claim 6, <b>May 28, 2004, 30 pages</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>ORTU-0007</b>	Application No. <b>10/761,096</b>
		Applicant <b>Raffa, et al.</b>	
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		Confirmation No. <b>2441</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>162</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Brief in Support of Defendant Kali's Motion for Summary Judgment of Invalidity Under the 35 U.S.C. § 102(b) Public-Use Bar, <b>May 28, 2004</b> , 16 pages	
	<b>163</b>	Expert Report of Howard T. Thaler, Ph.D., with Attached Exhibits 1 thru 7, <b>June 14, 2004</b>	
	<b>164</b>	<i>Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc.</i> , No. CV-02-5707(JCL) (D.N.J.), Defendant's Expert Report of Harry F. Manbeck, Jr. Under R.26(a)(2)(B) of the Federal Rules of Civil Procedure, with Attached Exhibits 1 thru 9, <b>June 14, 2004</b>	
	<b>165</b>	Expert Report of Charles E. Inturrisi, Ph.D., with Attached Exhibits 1 thru 15, <b>June 15, 2004</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	